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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,317	10/15/2003	Susan M. Freier	IBIS0009-101 (ISPH-0794)	8250
34138 7590 09/16/2008 ISIS PHARMACEUTICALS, INC 1896 RUTHERFORD ROAD CARLBAD, CA 92008				
EXAMINER				
VIVLEMORE, TRACY ANN				
ART UNIT		PAPER NUMBER		
1635				
MAIL DATE		DELIVERY MODE		
09/16/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/686,317

Applicant(s)

FREIER ET AL.

Examiner

Tracy Vivemore

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17 and 40-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection or objection not reiterated in this Action is withdrawn.

Claim Rejections - 35 USC § 102 & § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17 and 40-42 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Honkanen et al. (US 5,948,902).

The claims are directed to methods of selecting antisense-sequences by providing a set of antisense sequences complementary to a target nucleic acid

Art Unit: 1635

sequence, eliminating from the set sequences comprising 5'-GGGG-3' and 5'-GGA-3', selecting sequences comprising 5'-CCAC-3'; and synthesizing antisense oligonucleotides having the selected sequence. In specific embodiments the synthesized oligonucleotides are chimeric, have at least one 2'-substituted nucleotide and are tested *in vitro* for their ability to modulate the target nucleic acid.

Honkanen et al. disclose antisense oligonucleotides targeted to human PP5. In table 1 Honkanen et al. disclose a set of oligonucleotides, each of which is complementary to the PP5 target and is a chimeric oligonucleotide comprising a 2'-substituted nucleotide (see column 11). Three of the oligonucleotides synthesized contain the motif CCAC. Because these oligonucleotides were synthesized and tested for activity, this active synthesis step is considered to inherently include elimination of the recited negative motifs because these three sequences do not contain either the GGGG or GGA motifs.

Thus, Honkanen et al. disclose all limitations of and anticipate claims 17 and 40-42.

Claims 17 and 40-42 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over MacLeod (US 6,066,625).

The claims are directed to methods of selecting antisense-sequences by providing a set of antisense sequences complementary to a target nucleic acid sequence, eliminating from the set sequences comprising 5'-GGGG-3' and 5'-GGA-3', selecting sequences comprising 5'-CCAC-3'; and synthesizing antisense

oligonucleotides having the selected sequence. In specific embodiments the synthesized oligonucleotides are chimeric, have at least one 2'-substituted nucleotide and are tested *in vitro* for their ability to modulate the target nucleic acid.

MacLeod disclosed oligonucleotides targeted to DNA methyltransferase. In figure 2 and 3 MacLeod discloses preferred chimeric oligonucleotide sequences, including SEQ ID NOs: 10 and 13, which each contain the motif CCAC. These sequences were synthesized and tested to determine IC₅₀ in cultured lung cancer cells. Because these oligonucleotides were synthesized and tested for activity, this active synthesis step is considered to inherently include elimination of the recited negative motifs because these three sequences do not contain either the GGGG or GGA motifs.

Thus, MacLeod et al. disclose all limitations of and anticipate claims 17 and 40-42.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz, can be reached on 571-272-0763. The central FAX Number is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now

contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
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